Length of Time Needed for Institutional Review Board Approval or Exemption of Quality Improvement Projects Among Subset of US Training Programs

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“They [the IRB members] are lackluster in their responses and often seem to create roadblocks rather than a straight course to completion.”

- Study participant
Background: *Improving Quality of Care for Elderly Patients in the Educational Setting Study*

- **Purpose**
  Investigate the effectiveness of ABIM’s CoVE PIM to improve teaching and quality of care for elderly patients

- **Participants**
  Forty-six IM and FM residency programs

- **Methods and activities**
  - Pre and post tests of geriatric and quality improvement knowledge and attitudes (trainees and faculty)
  - Data collection at baseline and follow-up
    - Patient satisfaction surveys, patient chart abstractions, and a practice system assessment
  - CoVE PIM for intervention groups
Results

Of the 46 programs...

- 4 withdrew
  (IRB approval pursuit unknown)
- 4 exempt
- 8 expedited
- 30 full approval process

- 48% (22) programs were unable to begin the study within the pre-specified time zero period
Methods

- Calculated the length of time to completion
  - With same start point (June 15, 2006)
  - With program reported start point

- Brief online survey
  - Program actual start point (self-reported)
  - Comfort level with IRB
  - Overall IRB experience for this study
  - Free text about overall IRB experience coded and categorized by 4 independent reviewers

- Related time to completion to survey responses
Strengths and weaknesses

- **Strengths**
  - Multi-institutional study of IRB experience in training programs
  - IRB process with regards to a QI study

- **Weakness**
  - Data collected about the IRB experiences was collected 2 years later
  - Some data is still being collected
Results

- Time period to approval or exemption (n=42)
  - Range = < 1 - 56.5 weeks
  - Mean = 18.3 weeks
  - Median time = ~18 weeks

**Time to IRB approval**

(estimate based on June 15, 2006 start date)

<table>
<thead>
<tr>
<th>Number of weeks</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1 to 10</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>11 to 20</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>21 to 30</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>31 to 40</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>More than 40</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Number of programs
Results: Actual time to approval longer than expected

- Time period to approval or exemption (n=29)
  - Range = 3 - 58 weeks
  - Mean = 25.9 weeks
  - Median time = 25 weeks

- An average of 7.5 weeks LONGER than we had estimated

- Many people did not respond (26%)
Majority were at least “somewhat” comfortable navigating the IRB process  

- At the start of the study, what was your level of comfort with your ability to navigate the IRB process at your institution?

<table>
<thead>
<tr>
<th>Scale</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very comfortable</td>
<td>10 (25)</td>
</tr>
<tr>
<td>Somewhat comfortable</td>
<td>14 (35)</td>
</tr>
<tr>
<td>A little comfortable</td>
<td>8 (20)</td>
</tr>
<tr>
<td>Not at all comfortable</td>
<td>8 (20)</td>
</tr>
</tbody>
</table>

24 (60%)
Majority report IRB experience “excellent” or “good”

\[ n = 40 \]

- **How would you characterize your experience with your local IRB?**

<table>
<thead>
<tr>
<th>Scale</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>5</td>
</tr>
<tr>
<td>Poor</td>
<td>1</td>
</tr>
<tr>
<td>Poor</td>
<td>2</td>
</tr>
<tr>
<td>Poor</td>
<td>3</td>
</tr>
<tr>
<td>Poor</td>
<td>4</td>
</tr>
</tbody>
</table>

24 (57%)
Majority report IRB experience “good” or “excellent”, though comments don’t support this. \( n=40 \)

- **How would you characterize your experience with your local IRB?**

<table>
<thead>
<tr>
<th>Scale</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent 5</td>
<td>8 (19%)</td>
</tr>
<tr>
<td>4</td>
<td>16 (38%)</td>
</tr>
<tr>
<td>3</td>
<td>7 (17%)</td>
</tr>
<tr>
<td>2</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>1</td>
<td>6 (14%)</td>
</tr>
</tbody>
</table>

- **Please provide a rationale for your response**

<table>
<thead>
<tr>
<th>Comment type</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>17 (42.5%)</td>
</tr>
<tr>
<td>Negative</td>
<td>15 (37.5%)</td>
</tr>
<tr>
<td>Neutral</td>
<td>5 (12.5%)</td>
</tr>
<tr>
<td>No comment</td>
<td>3 (7.5%)</td>
</tr>
</tbody>
</table>
“The IRB made the entire process onerous in all respects, from the outset to closure. It was needlessly complicated, repetitive and unfriendly. I am loathe to pursue further IRB-required activities as a result. ...”

- Study participant
(took 27 weeks for IRB approval)
Comfort level related to weeks to approval

- Not at all comfortable
- A little comfortable
- Somewhat comfortable
- Very comfortable

Number of weeks to approval

Level of comfort

$r = -0.51$
Overall IRB experience related to weeks to approval

Number of weeks to approval vs. Rating of overall experience

$r = -0.60$
Methods for IRB pursuit

- All programs received...
  - A completed IRB template
  - Draft consent forms
    - Trainees and faculty
    - Patients (English and Spanish)
  - Participants instructed to contact their local IRB four months before study commencement
    - to learn about requirements
    - inquire about exemption eligibility (no identified data would be leaving the practice site)
Still the nagging question – why so long to approval?

- Why did **48%** of the programs start late? (after 4 months)
- Clearly there are other factors
- Further investigation is in process
  - Specific IRB processes and certifications necessary
  - Number of submissions
  - Specific reasons for need to re-submit
  - Learn from “best practice”
Conclusions and Recommendations

- Length of approval process time is highly variable across institutions.

- Comfort level with IRB process is related to the length of time that process takes.

- Standardization of IRB review specific to QI projects/studies:
  - Could help inexperienced clinician-educators with the process and to implement QI research projects.
  - Could also help those doing multi-institutional research better instruct study subjects.

- Encourage relationships with the IRB.
Bibliography